(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 July 2002 (04.07.2002)

PCT

(10) International Publication Number
WO 02/051490 A1

(51) International Patent Classification[7]: A61M 25/10

(21) International Application Number: PCT/CA00/01573

(22) International Filing Date:
22 December 2000 (22.12.2000)

(25) Filing Language: English

(26) Publication Language: English

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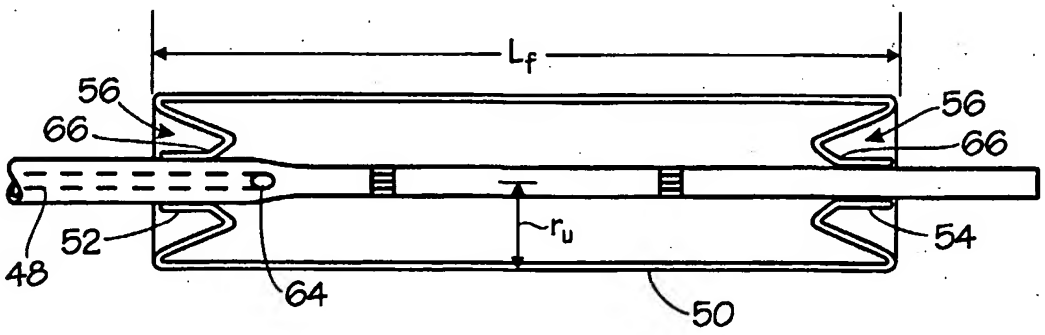
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: BALLOON FOR A BALLOON DILATION CATHETER AND STENT IMPLANTATION



(57) Abstract: A balloon for a balloon dilation catheter which may be used in a stent implantation system is disclosed. The generally tubular balloon has an end wall configuration which is designed to accommodate initial expansion of the balloon in an axial rather than radial manner. The ends walls of the balloon extend between the catheter and a central elongate portion. The balloon ends are sealingly attached to the catheter inwardly of the ends of the central portion so as to form an inverted portion with respect to the balloon. In this way, the extent to which the end walls can expand radially outwardly is limited as expansion of the balloon, if any occurs axially outwardly at the ends of the balloon. Thus, the central portion is permitted to expand uniformly radially. Axial expansion of the end walls eliminates or at least results in far less trauma to the portions of the vessel which extend beyond the targeted area. The stent implantation system includes a balloon catheter having a balloon as aforesaid with the inverted end wall configuration which promotes more uniform radial expansion of the balloon, and hence the associated stent.

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BALLOON FOR A BALLOON DILATION CATHETER AND STENT IMPLANTATION BALLOON

FIELD OF THE INVENTION

This invention is directed to a catheter that utilizes a balloon to dilate structures or stenosis within the human body. More particularly, this invention relates generally to improvements in apparatus for uniformly implanting a stent and, more particularly, to improved uniform stent implantation systems wherein radial expansion is controlled. The stent implantation system includes a balloon catheter having a balloon with a novel end wall configuration which promotes more uniform radial expansion of the balloon, and hence the associated stent.

BACKGROUND OF THE INVENTION

Catheters are tube-like members inserted into the body for diagnostic or therapeutic reasons. One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of cholesterol fats or atherosclerotic plaque. In 1976 the first marketable PTCA apparatus consisted of a small catheter with a single balloon port and no central lumen, that is, a so-called "fixed wire" system, which terminated in lateral openings at the distal end thereof. This system, which is the subject of U.S. Pat. No. 4,195,637, was designed by Dr. Gruntzig. The fixed wire catheter system disclosed in U.S. Pat. No. 4,195,637 comprises a balloon dilatation catheter and a low friction guide catheter consisting of one tubular member fitted into a more rigid, shrunk-on tubular member that is not co-extensive. The distal end of the balloon dilatation catheter has a flexible tip advantageously fabricated from a spring steel wire. In 1980-1981 Dr. John Simpson, working at Stanford University, began to modify the fixed wire system and eventually developed a catheter with a free central lumen for movable guide wires. This catheter system is the subject of U.S. Pat. No. 4,323,071 issued to Simpson et al. By use of such a movable wire system, one could more readily select the desired coronary artery and reach smaller branches since the movable guide wires are inherently smaller and more flexible than the fixed wire system. The catheter is subsequently tracked over the guide wire to the stenosis. The balloon at the distal end of the catheter is then inflated causing the site of the stenosis to widen. After the

balloon is deflated, the catheter is withdrawn over the guidewire and another catheter can be slid into place over it if necessary.

In a particular procedure for exchanging catheters, the guide wire is left in place to protect the artery during the exchange. The guide wire is left in the artery because of complications that can arise when removing the guide wire, e.g., when the distal tip of the guide wire lifts a lesion flap, when the vessel spasms or abruptly closes making wire advancement impossible, or when placement of the guide wire simply takes too much time. To avoid these complications, the wire in this procedure is typically maintained in the vessel while the catheter exchange takes place.

Two techniques are generally employed for exchanging catheters when the guide wire is maintained in the artery. The first technique is used with catheters in which the guide wire lumen extends the full length of the catheter shaft. These are often referred to as "over-the-wire" catheters. When the "over-the-wire" catheter is withdrawn from the patient, guide wire position is maintained by holding the guide wire at its proximal end. To maintain a grip on the guide wire until the entire catheter is withdrawn from the patient, the guide wire must be long enough so that the proximal end of the guide wire can be held in place until the distal end of the catheter exits the patient. After the distal end of the catheter has been withdrawn from the patient, the grip at the proximal end of the guide wire may be withdrawn and the guide wire can be firmly held distal to the distal end of the catheter. The catheter can then be completely removed from the patient. The same procedure is performed in reverse to insert a different catheter into the patient. The following are examples of over-the-wire catheters are shown in the following patents: in U.S. Pat. No. 4,917,666 issued to Solar and Roucher; U.S. Pat. No. 4,323,071 issued to Simpson et al.

In order to simplify catheter exchange, a second technique was developed which uses a "rapid exchange" catheter design. In the "rapid exchange" catheter, the guide wire lumen does not extend the full length of the catheter shaft. Instead, the guide wire exits the catheter shaft at some point near the distal end of the catheter. The remaining length of the guide wire runs alongside the catheter shaft until both the catheter and the guide wire exit the patient. This reduces the necessary length of the

guide wire in comparison to the length required by the "over-the-wire" catheters. Various versions of rapid exchange catheters, either coaxial or biaxial, are shown in the following U.S Patents: Nos. 4,762,129 and 5,232,445 issued to Bonzel; Nos. 5,040,548 and 5,061,273 issued to Yock; No. 4,748,982 issued to Horzewski, et al.; No. 4,988,356 issued to Crittenden; No. 5,135,535 issued to Kramer; No. 5,180,367 to Kontos; No. 5,571,087 issued to Ressemann et al; and No. 5,549,557 issued to Steinke et al.

In each design, the balloon has a generally cylindrical shape, positioned in a concentric manner in relation to the catheter shaft, and bonded distally and proximally to the shaft, as shown in Fig. 1A. In general, the material from which the balloons are made renders them one of the following three categories: compliant, which are relatively stretchable; non-compliant, which are not stretchable; and semi-compliant, which have moderate stretchability. Ideally, inflation of a concentrically mounted balloon as shown in Fig. 1B results in a uniform force circumferentially applied to the stenotic lesion. However, the structure or morphology of the lesion is rarely uniform so as to permit uniform radial expansion as shown in Fig. 1B, as harder portions will require more force to dilate than will softer areas. This has necessitated the practice of inflating the balloon at very high pressures, causing over-distention, dissection, and tearing. In addition, at high pressure, a dilatation balloon may rupture, resulting in serious complications. Thus, there is a need for a balloon catheter which can apply a focussed, variable force for dilatation, at lower pressures.

In such angioplasty procedures, there may be restenosis of the artery, which necessitates either another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the dilated area. To assist in the prevention of restenosis and to strengthen the dilated area, a physician can implant an intravascular prosthesis, generally called a stent, to maintain vascular patency inside the artery at the site of the lesion. Stents are also used to repair vessels having a flap or dissection or to generally strengthen a weakened section of a vessel. The stent is expandable to a larger diameter, often by the balloon portion of the dilatation catheter. Stents delivered to a restricted coronary artery, expanded to a

larger diameter by a balloon catheter, and left in place within the artery at the site of the dilated lesion are shown, for example, in U.S. Pat. No. 4,740,207 (Kreamer) and U.S. Pat. No. 5,007,926 (Derbyshire).

Although stents have been used effectively for some time, the effectiveness of a stent can be diminished if it is not uniformly implanted within the vessel. In the prior art, stents are placed along the central portion or working length L_f of a balloon as shown in Fig. 2A. Such balloons tend to have non-uniform radial expansion due to the increased restriction the stent imposes on the working (central) length of the balloon. Consequently, as shown in Figs. 2B and 2C, the balloon expands first at the proximal and distal balloon ends along the path of least resistance, i.e., towards the distal and proximal ends of the balloon, causing the initial state of the inflating balloon to resemble a "dog bone". Thus, when the balloon expands in this "dog bone" fashion, the proximal and distal regions of the balloon over expand to form a characteristic "dog bone" shape, the stent itself does not expand uniformly which may result in the stent being improperly implanted. In addition, the inflation of both distal and proximal ends of the balloon which extend beyond the respective ends of the stent will cause trauma to a vessel wall, which might have been healthy, due to radial contact therewith.

Accordingly, those concerned with the design, development, and use of stent implantation systems have long recognized the desirability and need for further improvements in systems for uniformly implanting a stent in order to maximize stent performance. In this regard, what has been needed and, heretofore unavailable, is a stent delivery system which controls the radial expansion of the stent along its entire length to ensure uniform expansion and minimize vessel wall trauma resulting from stent "dog bone" expansion. U.S. Pat. No. 5,409,495 to Osborn for "Apparatus for Uniformly Implanting a Stent" discloses elastic restraining bands which exert a force at the proximal and distal ends of the balloon equal and opposite to that generated by the combined resistance of the sleeve and the stent tending to deform the balloon. In this way, the uneven expansion (end effects) are limited when the balloon is expanded which, in turn, inhibits a "dog boning" deformation at the proximal and distal regions of the balloon.

SUMMARY OF THE INVENTION

The present invention overcomes the above identified disadvantages by providing a novel end configuration for the ends walls of the balloon which extend between the catheter and the central elongate portion. In general, the balloon ends are sealingly attached to the catheter inwardly of the ends of the central portion so as to form an inverted portion with respect to the balloon. In this way, the extent to which the end walls can expand radially outwardly is limited as expansion of the balloon, if any occurs axially outwardly at the ends of the balloon. Thus, the central portion is permitted to expand uniformly radially. Axial expansion of the end walls eliminates or at least results in far less trauma to the portions of the vessel which extend beyond the targeted area.

More specifically, there is provided in one aspect of the invention, an apparatus for insertion into a biological conduit, comprising:

a catheter tube having a proximal and a distal end;

a balloon mounted at or near the distal end of the catheter tube, the balloon comprising

a radially expandable and collapsible central portion, which when expanded, assumes a substantially cylindrical configuration; and

flexible end walls integrally formed with the central portion at each end thereof, each flexible end wall being attached to the catheter tube at a location which is axially inwardly of a respective end of the central portion of the balloon; and

means for inflating and collapsing the balloon.

In an alternate embodiment, only one flexible end wall is attached the catheter tube at a location which is axially inwardly of respective end of the central portion of the balloon whereas the other flexible end wall is attached to the catheter tube at a location which is axially outwardly of the other end of the central portion of the balloon.

Since the inverted balloon end configuration can be employed in a variety of balloon catheter arrangements including but not limited to bifurcated balloon catheters, the

present invention also contemplates a configuration for an end wall of a balloon of a balloon catheter, which end wall extends between the catheter and an end of a radially expandable and collapsible wall which forms the functional length of the balloon, the end wall being attached to the catheter at a location which is axially inwardly of the end of the radially expandable and collapsible wall with respect to the balloon.

According to another aspect of the invention, there is provided a balloon for use in a catheter system comprising a generally cylindrical wall which forms the functional length of the balloon during expansion, the cylindrical wall being attached to the catheter via a pair of radial walls at each end of the functional length of the balloon, wherein a portion of at least one of the radial walls which is connected to the catheter is disposed axially inwardly of the end of the functional length of the balloon to which the radial wall is attached.

The present invention also provides an improved apparatus for controlling the radial expansion of a catheter balloon used to deliver a stent, in order to enhance uniform implantation of the stent. In this regard, there is provided a stent delivery system comprising in combination:

a balloon catheter comprising

a catheter tube having a proximal and a distal end;

a balloon mounted at or near said distal end of the catheter tube, said balloon comprising

a radially expandable and collapsible central portion, which when expanded, assumes a substantially cylindrical configuration; and

flexible end walls integrally formed with the central portion at each end thereof, each flexible end wall being attached to the catheter tube at a location which is axially inwardly of a respective end of the central portion of the balloon; and

means for inflating and collapsing the balloon; and

a stent mounted on the central portion of the balloon when the balloon is collapsed, the stent being radially expandable upon expansion of the balloon.

In each embodiment, during inflation of the balloon, the inverted portions at the proximal and distal ends of the balloon expand axially and do not extend radially beyond the expanding diameter of the central or working portion. In this way, the uneven expansion (end effects) are limited as the balloon is being expanded which, in turn, inhibits a "dog boning" deformation at the proximal and distal regions of the balloon present in the prior art.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A to 1C are side views showing a typical dilatation balloon catheter, according to the prior art, expanding from its "collapsed" state to an "expanded" state;

Figs. 2A to 2E are cross-sectional side views showing the operation of a dilatation balloon catheter of Figs. 1A to 1C in a prior art stent delivery system;

Fig. 3 is a perspective view of the balloon dilation catheter in accordance with the present invention;

Figs. 4A to 4C are cross-sectional side views showing the operation of the dilatation balloon catheter of Fig. 3;

Figs. 5A and 5B are enlarged cross-sectional side views detailing the manner in which the radial end walls of the balloon may react in response to interior pressure in the balloon;

Fig. 6 is a cross-sectional side view showing a variant of the balloon dilation catheter in accordance with the present invention;

Fig. 7 is a cross-sectional side view showing another variant of the balloon dilation catheter in accordance with the present invention;

Figs. 8A and 8B are a cross-sectional side views showing further variants of the balloon dilation catheter in accordance with the present invention; and

Figs. 9A - 9C are a cross-sectional side views showing the balloon dilation catheter of Figs. 4A - 4C being used as part of an intravascular catheter system for implanting and expanding a stent in a body lumen.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1A-1C shows a typical dilatation balloon catheter 10, according to the prior art, expanding from its "collapsed" state to an "expanded" state.

In Fig. 1A, the balloon 12 is collapsed, having an optimal initial profile radius r_i for insertion into the blood vessel . The balloon 12 is attached to a catheter tube 14 at its proximal and distal ends 16,18 which are generally shaped symmetrical to one another. The shape of the balloon 12 in its collapsed state is somewhat dependent on its nature, that being compliant, semi-compliant or non-compliant. When a semi- or non-compliant balloon is collapsed, it assumes a flattened configuration which is curled circumferentially around the catheter tube 14. Compliant balloons tend to conform to the shape of the catheter tube 14. Regardless, the balloon 12 will have a designed operational or functional length L_f which is separated from the balloon ends 16,18 by integrally formed tapered portions 20. The functional length L_f is that portion of the balloon 12 that remains substantially parallel to the catheter/balloon axis 22. Length L is the expandable portion of the balloon 12 which is generally equal to the functional length L_f plus the length of tapered portions 20.

In the second stage, shown particularly by Fig. 1B, inflation of the balloon 12 expands the initial profile radius r_i to secondary profile radius r_s, which is generally uniform along the functional length L_f of the balloon 12. During use, radial pressure is applied to the interior walls of the blood vessel (not shown) along the functional length L_f when the balloon 12 is in the expanded configuration. Upon further expansion as seen in Fig. 1C, a semi-compliant or compliant balloon 12 will attain a rounded longitudinal cross-section with a varied radius r_v. The previously tapered portions 20 become curved and extend further centrally of the balloon 12 as the functional length L_f shortens.

Figs. 2A-2E show the effects of using such a balloon catheter 10 in a stent delivery system 30. Fig. 2A shows the balloon 12 in the collapsed state with a stent 32 placed over the balloon 12. As best observed in Fig. 2B, initial inflation of the balloon 12 causes the proximal and distal ends 16,18 of the balloon 12 to inflate first in a dog bone fashion as the stent 32 restricts the expansion of the central balloon

portion. This occurs because the balloon ends (i.e. the points of attachment of the balloon ends and the catheter) extend outwardly beyond the functional length L_f which has been selected based on the desired length L_s of the stent 32 to be implanted. Further pressurization of the balloon 12 beyond the amount which will cause the stent 32 to deform radially outwardly causes the stent to expand, but due to the bulging ends 16,18 of balloon 12, expansion commences in a dog bone fashion at the proximal and distal ends 34,36 of the stent 32 as shown in Fig. 2C. Such non-uniform radial expansion of the stent 32 makes it unlikely that the stent 32 will achieve a substantially uniform diameter as ideally shown in Fig. 2D. The stent 32 is likely to fall short of radially uniform (still in a dog bone configuration) or, in the case of semi-compliant and compliant balloons, will be caused to over-expand in the central portion as shown in Fig. 2E as the balloon 12 is over-inflated.

FIG. 3 illustrates a balloon dilation catheter in accordance with the present invention, shown generally by the reference numeral 40. The catheter 40 has a proximal end 42, a distal end 44, an axis 46 and a catheter tube 47 surrounding at least one inflation lumen 48. The inflation lumen 48 extends between the ends 42, 44 along the axis 46. The inflation lumen 48 communicates fluid to and from the balloon 50 for its inflation and deflation. The catheter shown is of the "rapid exchange" type, wherein the guide wire 51 is separate from the catheter tube 47 until near the distal end 44 where it enters the catheter tube 47 and exits axially out the distal end 44. This guide wire 51 is not shown in catheter arrangements diagrammed in Figs.4A-9C for sake of clarity.

The balloon 50 is mounted on the distal end 44 of the catheter 40. The balloon 50 has a proximal end 52 and a distal end 54. In general, the ends 52,54 of the balloon 50 are bonded, fused, adhered or otherwise attached to the catheter tube 47 in a fluid tight manner by techniques known in the art. The balloon 50 is inflatable to expand from a collapsed configuration to an expanded configuration. The balloon 50 is deflatable after inflation to selectively return to the collapsed configuration for removal. The balloon 50 can be fabricated from a flexible, fluid impermeable material suited for the specific application. In this regard, the balloon can be made from a flexible polymer such as nylon, PET, PE, etc.; silicone; latex; urethane; a

polysiloxane modified styrene-ethylene/butylene-styrene block copolymer (SEBS); or like material. The term "flexible" when used herein to refer to the balloon material has slightly differing connotations, depending on whether the balloon design is compliant, semi-compliant, or non-compliant. The balloon must be able to expand radially from a reduced insertion diameter to an inflated diameter and to deflate to the insertion diameter for withdrawal. In the case of a non-compliant balloon, the balloon itself is more akin to a small inflatable bag rather than a balloon per se in that while flexible it is not significantly stretchable. It is formed originally as a cylindrical shape having a radius equivalent to the maximum or design radius which it is expected to achieve without significantly encroaching on its failure limits. It must be flexible so that it can be voided of fluid and collapsed. When collapsed, it must be flattenable so as to enable the balloon to be folded or wrapped around the catheter tube in a considerably reduced diameter for navigation through bodily vessels or to enable an unexpanded stent to be placed thereover and crimped for later deployment (as will be described in greater detail hereinbelow). Semi-compliant are moderately stretchable so their flexibility is generally a combination of stretchability and foldability. The flexibility of stretchable balloons is a result of their stretchability.

While the catheter 40 is adapted for percutaneous transluminal coronary angioplasty procedures (PTCA), it will be appreciated that a balloon in accordance with the present invention can be used in conjunction with many other procedures including the implantation and repair of intraluminal (e.g. intravascular) prostheses. It will also be appreciated that the balloon 50 and catheter 40 of the present invention have multiple applications. Such applications include diagnostic procedures such as cardiological and vascular imaging. Other uses include laser and mechanical ablation of biological tissue, transluminal medication delivery, and various other interventional, diagnostic and corrective procedures.

The terms "collapsed" and "collapsed configuration" indicate that the balloon 50 is not fully expanded. The collapsed balloon 50 holds a volume of fluid which is significantly less than the volume of fluid held by the balloon 50 when expanded. A typical expanded balloon 50 may hold pressures of 10-20 atm., for example. A collapsed balloon may hold pressure of less than 1 atm. It will be appreciated that

the pressures at which the balloon inflates and deflates may vary in accordance with the particular catheter and balloon design requirements.

The balloon 50 of FIG. 3 is shown in operation and in greater detail in Figs. 4A-4C. In Fig. 4A, the balloon 50 is shown in its collapsed configuration, having an optimal initial profile radius r_i for insertion into the blood vessel. In this embodiment, the proximal and distal ends 52,54 of balloon 50 are bonded, attached or otherwise affixed in a sealing fashion to the catheter tube 47 so as to provide an inverted portion 56 which underlies each end 58 of the functional length L_f of the balloon 50. Accordingly, the overall length L of the balloon 50 is equal to or substantially equal to its functional length L_f. In the case of a non-compliant or semi-compliant balloon, when the balloon 50 is collapsed, it assumes a flattened configuration and is wrapped around both the catheter tube 47. A compliant balloon naturally biases itself into a substantially fully-deflated state against the catheter tube 47 in absence of pressurization.

The balloon 50 is inflated by introducing fluid under pressure, such as for example via syringe 60 shown in Fig. 3. Fluid from the syringe 60 is communicated through the inflation lumen 48 in the catheter tube 47 and interiorly of the balloon 50 through port 64 (see Figs. 4A-4C). Port 64 is disposed between the sealed ends 52,54 of the balloon 50. The pressurized fluid causes the balloon 50 to expand radially as shown in Fig. 4B. Because the points 66 from which the balloon ends 52,54 extend or are attached to the catheter are located inwardly of the ends 58 of the functional length L_f of the balloon 50 and radially therebelow, the extent to which the originally inverted portions 56 can expand radially outwardly is limited if not eliminated and the balloon 50 expands with a uniform radius r_u substantially along its entire functional length L_f, i.e. the functional length L_f maintains a generally cylindrical shape. In the case of a non-compliant balloon, the balloon 50 is designed such that it reaches its maximum (design) radius r_{max} either before the inverted portions 56 fully elongate or at about the same time as shown in Fig. 4C. If and when fully elongated, inverted portions 56 generally form an inwardly disposed, frustoconically-shaped radial end wall. Except where otherwise specified, the term "inwardly" and "outwardly" as used herein are generally relative to the longitudinal center of the balloon.

The expansion of the balloon 50 is shown in greater detail in Figs. 5A and 5B. As the balloon 50 starts to expand radially outwardly against a restrictive element 68 (which may be a stent as shown or against a portion of a vessel wall), the internal pressure will likely cause the inverted portion 56 to expand axially outwardly to 56' as there will be less resistance to expansion in that direction. The rate of expansion (to its maximum axial extent) will of course depend on whether the balloon is compliant, semi-compliant or non-compliant. However, as can be seen, because the expansion of the initially extraneous material is in an axially outward direction, there will be little if any dog boning that will occur and thus the expansion of the central portion 69 of the balloon 50 will occur uniformly radially.

A variation of the balloon is shown in Fig. 6 in an intermediate expansion state (greater than collapsed, but less than fully expanded). In this embodiment, balloon 70 is provided at both ends with additional axial wall capacity in the form of a multiply folded or bellows-type wall 72. The walls 72 extend from attachment locations or points 66 to the extreme ends 58 of the function length L_f. Since attachment points 66 are axially inward of the ends 58 of the function length L_f, the extent to which the radial walls 72 can expand radially outward is limited as expansion will occur primarily in the axial direction. The additional overlappings in the walls 72 permits greater radial expansion of the function length L_f portion of the balloon 70 as they straighten.

A further embodiment is illustrated in Fig. 7 which shows balloon 75 in its expanded state similar to balloon 50 shown in Fig. 4C. However, in this case, the proximal and distal ends 52,54 of the balloon 75 are sealingly attached along portions of the catheter tube 47 axially inwardly of the points 66 from which the radial wall or inverted portion 76 extends.

Figs. 8A and 8B show yet further embodiments of the present invention in semi-expanded states wherein only one end of the respective balloons 80,90 includes the inverted portion 82, 92 whereas the opposite end has a conventional tapered portion 84,94. In Fig. 8A, the inverted portion 82 extends from the proximal end 86 of the functional length portion L_f to attachment point 66 which is located axially inwardly

of the proximal end 86. The tapered portion 84 extends from the distal end 88 of the functional length portion L_f to attachment point 67 which is located axially outwardly of the distal end 88. In Fig. 8B, the inverted portion 92 extends from the distal end 96 of the functional length portion L_f to attachment point 66 which is located axially inwardly of the distal end 96. The tapered portion 94 extends from the proximal end 98 of the functional length portion L_f to attachment point 67 which is located axially outwardly of the proximal end 88.

Although the catheter 40 is adapted for PTCA, it will be appreciated that a balloon in accordance with the present invention can be used in conjunction with many other procedures including the implantation and repair of intraluminal (e.g. intravascular) prostheses.

In an intravascular catheter system for implanting and expanding a stent in a body lumen, the distal end of which is shown in Figs. 9A-9C, catheter 100 includes catheter tube 102 through which inflation lumen 104 communicates fluid interiorly of the balloon 110 through port 106. Proximal and distal ends 112,114 of the balloon 110 are sealingly attached to the catheter tube 102 so as to include inverted portions 116 which will constitute the end walls of the balloon 110 during expansion. A stent 120, equivalent in length to the functional length L_f of balloon 110, is placed or crimped over balloon 110 when in its collapsed state. A guide wire 51 (as shown in Fig. 3) is used to position the balloon 110 and stent 120 within the vessel. The stent 120 may be any one of the variety of commercially available stents, however, it is preferred that the stent be of the type that shown and described in Applicant's international application No. PCT/CA99/00632 filed July 12, 1999 and entitled Expandable Endovascular Medical Tubular Stent or No. PCT/CA00/00035 filed January 21, 2000 and entitled Expandable Intravascular Tubular Stent.

As best observed in Figs. 9B and 9C, when balloon 110 inflates, it expands radially. The inverted portions 116 initially expand axially outwardly, which is along the path of least resistance. This novel approach eliminates the "dog boning" affect that is common with prior art devices as described hereinabove. In this way, the stent 120

is uniformly expanded to its implantation diameter and properly placed within the vasculature of a patient.

It will be understood that the embodiments described herein are merely exemplary and that a person skilled in the art may make many variations and modifications without departing from the spirit and scope of the invention. All such modifications and variations are intended to be included within the scope of the invention as defined in the appended claims.

I CLAIM:

1. An apparatus for insertion into a biological conduit, comprising:
a catheter tube having a proximal and a distal end;
a balloon mounted at or near said distal end of said catheter tube, said balloon comprising
a radially expandable and collapsible central portion, which when expanded, assumes a substantially cylindrical configuration; and
flexible end walls integrally formed with said central portion at each end thereof, each said flexible end wall sealingly attached to catheter tube at a location which is axially inwardly of a respective end of said central portion of said balloon; and
means for inflating and collapsing said balloon.

2. The apparatus as claimed in claim 1, wherein each flexible end wall is sealingly secured to said catheter tube along via an attachment section formed integrally with said flexible end wall.

3. The apparatus as claimed in claim 2, wherein said attachment section is disposed axially outwardly of said location.

4. The apparatus as claimed in claim 2, wherein said attachment section is disposed axially inwardly of said location.

5. The apparatus as claimed in claim 1, wherein each said flexible end wall is radially expandable and collapsible.

6. The apparatus as claimed in claim 5, wherein each said flexible end wall is folded when the balloon is collapsed.

7. The apparatus as claimed in claim 5, wherein each said flexible end wall is folded a plurality of times when the balloon is collapsed.

8. The apparatus as claimed in claim 5, wherein each said flexible end wall is in the form of a bellows.

9. The apparatus as claimed in claim 1, wherein said means for inflating and collapsing said balloon comprises an inflation lumen disposed within said catheter tube for communicating a supply of fluid to and from said balloon through a port in said catheter tube, said port being disposed interiorly of said balloon.

10. The apparatus as claimed in claim 1, wherein each said flexible end wall forms an axially inwardly pointing frustoconical wall when said balloon is fully expanded.

11. The apparatus as claimed in claim 1, further comprising a stent mounted on said central portion of said balloon when said balloon is collapsed, said stent being radially expandable upon expansion of said balloon.

12. The apparatus as claimed in claim 11, wherein the stent is crimped over said central portion of said balloon when said balloon is collapsed.

13. The apparatus as claimed in any one of claims 1 to 12, further comprising a guide wire for facilitating positioning of said distal end of said catheter tube.

14. A configuration for an end wall of a balloon of a balloon catheter which end wall extends between the catheter and an end of a radially expandable and collapsible wall which forms the functional length of the balloon, the end wall being sealingly attached to said catheter at a location which is axially inwardly of said end of said radially expandable and collapsible wall with respect to said balloon.

15. An apparatus for insertion into a biological conduit, comprising:

a catheter tube having a proximal and a distal end;

a balloon mounted at or near said distal end of said catheter tube, said balloon comprising

a radially expandable and collapsible central portion, which when expanded, assumes a substantially cylindrical configuration; and

flexible end walls integrally formed with said central portion at each end thereof, at least one of said flexible end walls being attached to said catheter tube at a location which is axially inwardly of a respective end of said central portion of said balloon; and

means for inflating and collapsing said balloon.

16. The apparatus as claimed in claim 15, wherein said at least one flexible end wall is secured in fluid tight relation to said catheter tube along via an attachment section formed integrally with said at least one flexible end wall.

17. The apparatus as claimed in claim 16, wherein said attachment section is disposed axially outwardly of said location.

18. The apparatus as claimed in claim 16, wherein said attachment section is disposed axially inwardly of said location.

19. The apparatus of claim 15, wherein one flexible end wall is connected to or integrally formed with the catheter tube at a location which is axially outwardly of another end of said central portion of said balloon.

20. The apparatus of claim 19, wherein said one flexible end wall is disposed proximal said proximal end of said catheter tube.

21. The apparatus of claim 19, wherein said one flexible end wall is disposed distal said proximal end of said catheter tube.

22. The apparatus as claimed in claim 15, wherein said at least one flexible end wall is radially expandable and collapsible.

23. The apparatus as claimed in claim 22, wherein each said at least one flexible end wall is folded when the balloon is collapsed.

24. The apparatus as claimed in claim 22, wherein each said at least one flexible end wall is folded a plurality of times when the balloon is collapsed.

25. The apparatus as claimed in claim 22, wherein each said at least one flexible end wall is in the form of a bellows.

26. The apparatus as claimed in claim 15, wherein said means for inflating and collapsing said balloon comprises at least one inflation lumen disposed within said catheter tube for communicating a supply of fluid to and from said balloon through a port in said catheter tube, said port being disposed interiorly of said balloon.

27. The apparatus as claimed in claim 15 further comprising a stent mounted on said central portion of said balloon when said balloon is collapsed, said stent being radially expandable upon expansion of said balloon.

28. The apparatus as claimed in claim 27, wherein the stent is crimped over said central portion of said balloon when said balloon is collapsed.

29. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is fabricated from a flexible polymer.

30. The apparatus as claimed in claim 29, wherein the flexible polymer is nylon, PET, or PE.

31. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is fabricated of silicone.

32. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is fabricated of latex.

33. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is fabricated of urethane.

34. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is fabricated of a polysiloxane modified styrene-ethylene/butylene-styrene block copolymer.

35. The apparatus as claimed in claim 1 or claim 15, wherein said balloon is selected from the group consisting of a compliant balloon, a semi-compliant balloon and a non-compliant balloon.

36. The apparatus as claimed in any one of claims 15 to 35, further comprising a guide wire for facilitating positioning of said distal end of said catheter tube.

37. A stent delivery system comprising in combination:

a balloon catheter comprising

a catheter tube having a proximal and a distal end;

a balloon mounted at or near said distal end of said catheter tube, said balloon comprising

a radially expandable and collapsible central portion, which when expanded, assumes a substantially cylindrical configuration; and

flexible end walls integrally formed with said central portion at each end thereof, at least one of said flexible end walls being attached to the catheter tube at a location which is axially inwardly of a respective end of said central portion of said balloon; and

means for inflating and collapsing said balloon; and

a stent mounted on said central portion of said balloon when said balloon is collapsed, said stent being radially expandable upon expansion of said balloon.

38. The apparatus as claimed in claim 37, further comprising a guide wire for facilitating positioning of said distal end of said catheter tube.

39. A balloon for use in a catheter system comprising a generally cylindrical wall which forms the functional length of the balloon during expansion, said cylindrical wall being attached to the catheter via a pair of end walls at each end of the functional length of the balloon, wherein a portion of at least one of the end walls which is connected to the catheter is disposed axially inwardly of the end of the functional length of the balloon to which the end wall is attached.

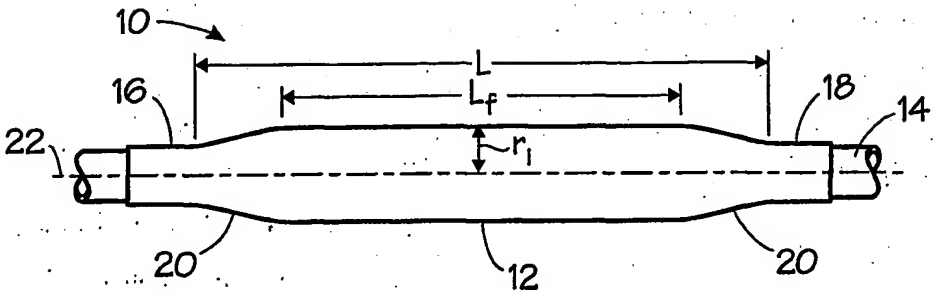

Fig. 1A
PRIOR ART

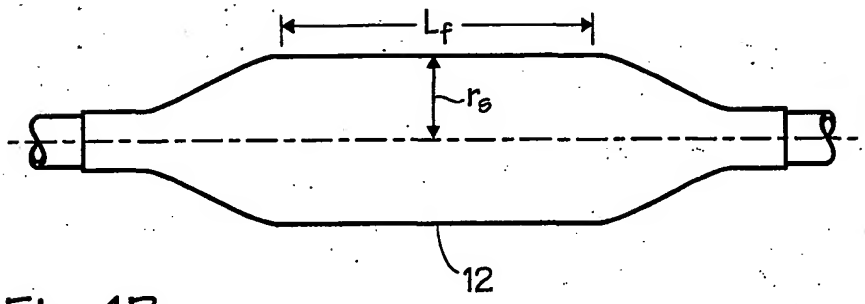

Fig. 1B
PRIOR ART

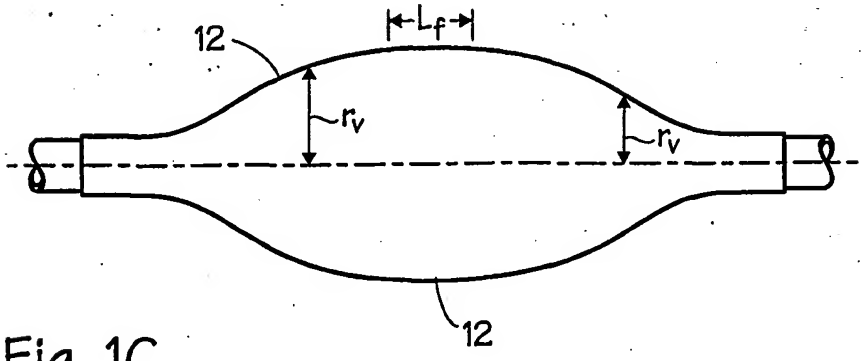

Fig. 1C
PRIOR ART

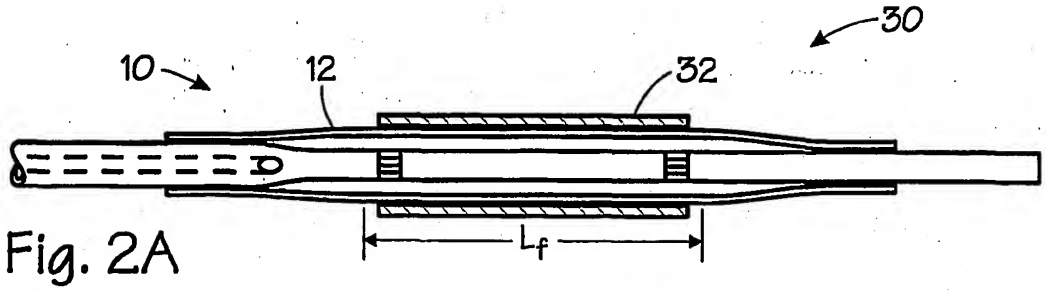

Fig. 2A
PRIOR ART

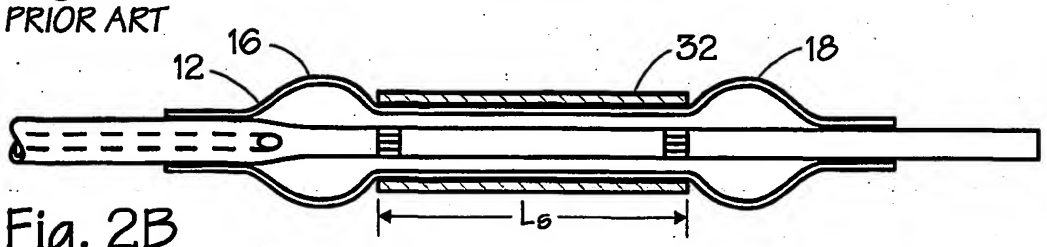

Fig. 2B
PRIOR ART

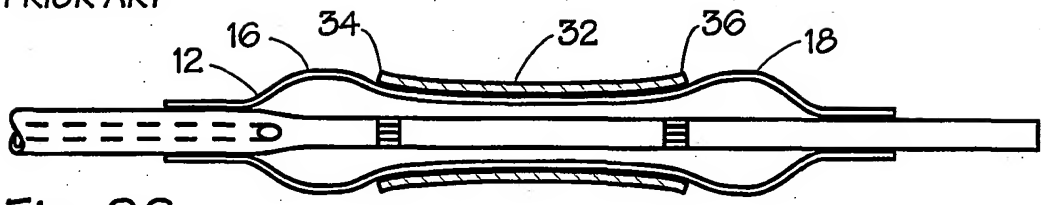

Fig. 2C
PRIOR ART

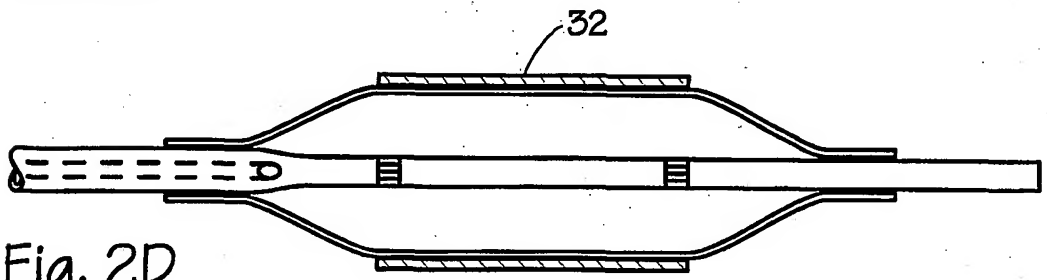

Fig. 2D
PRIOR ART

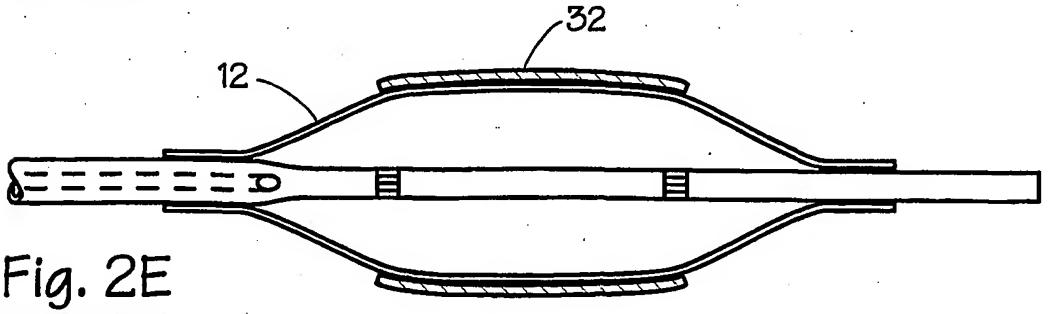

Fig. 2E
PRIOR ART

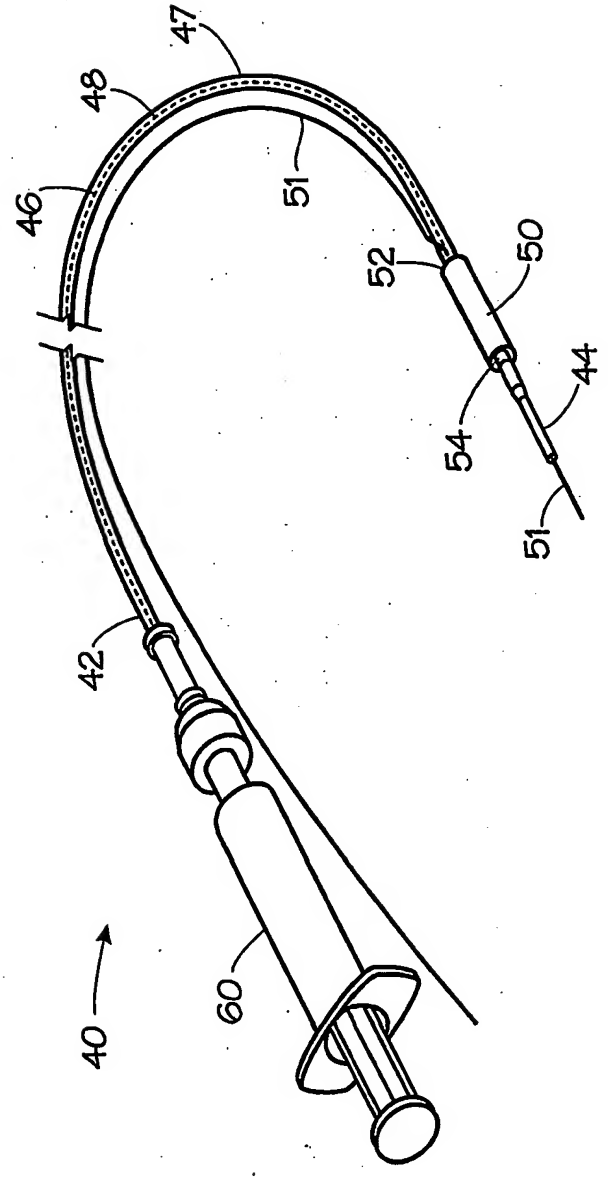

Fig. 3

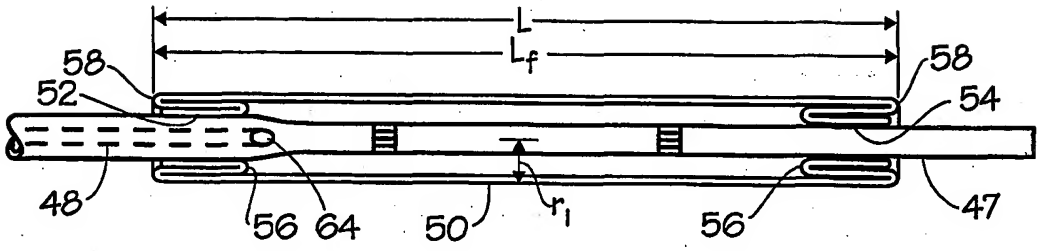

Fig. 4A

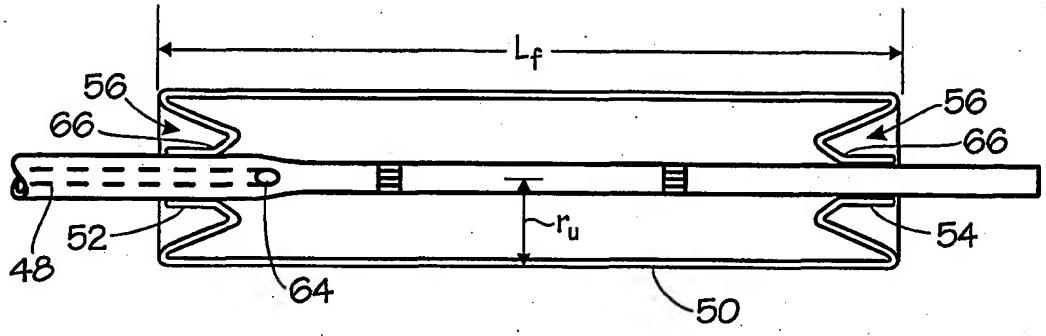

Fig. 4B

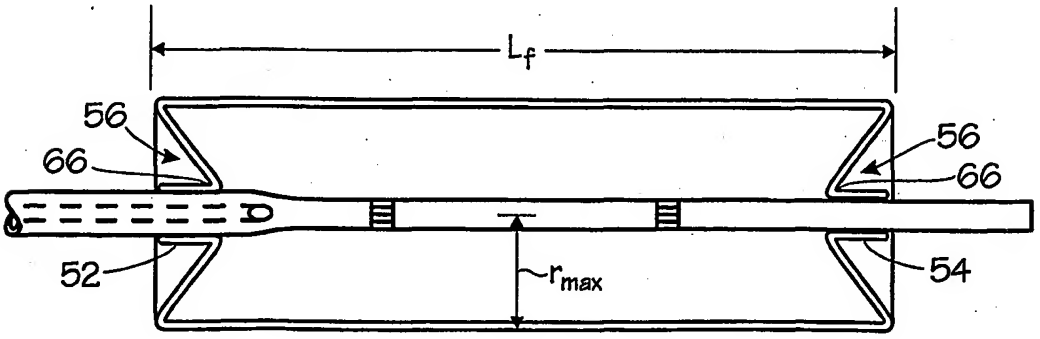

Fig. 4C

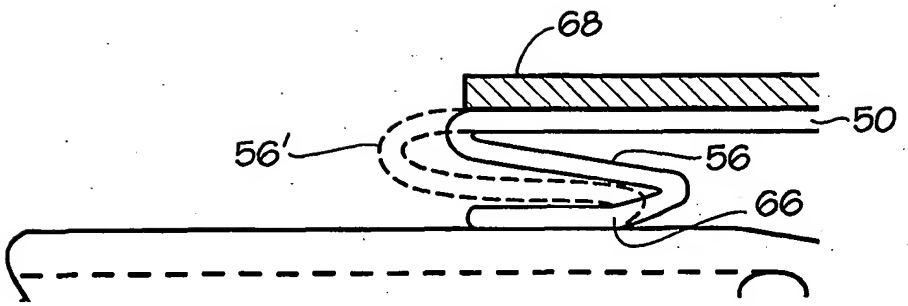

Fig. 5A

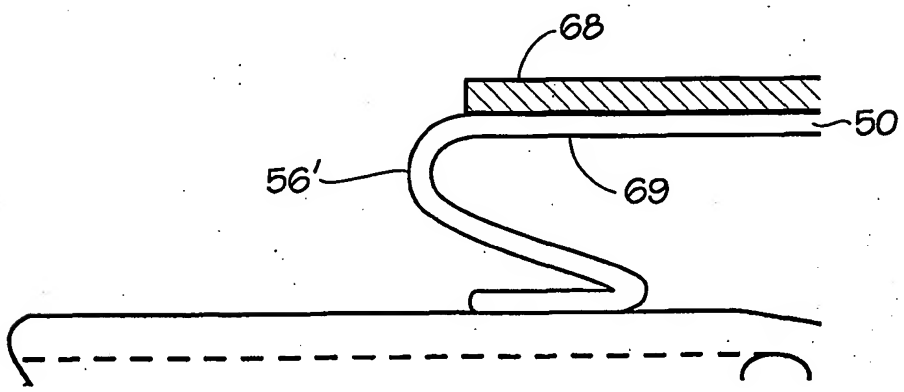

Fig. 5B

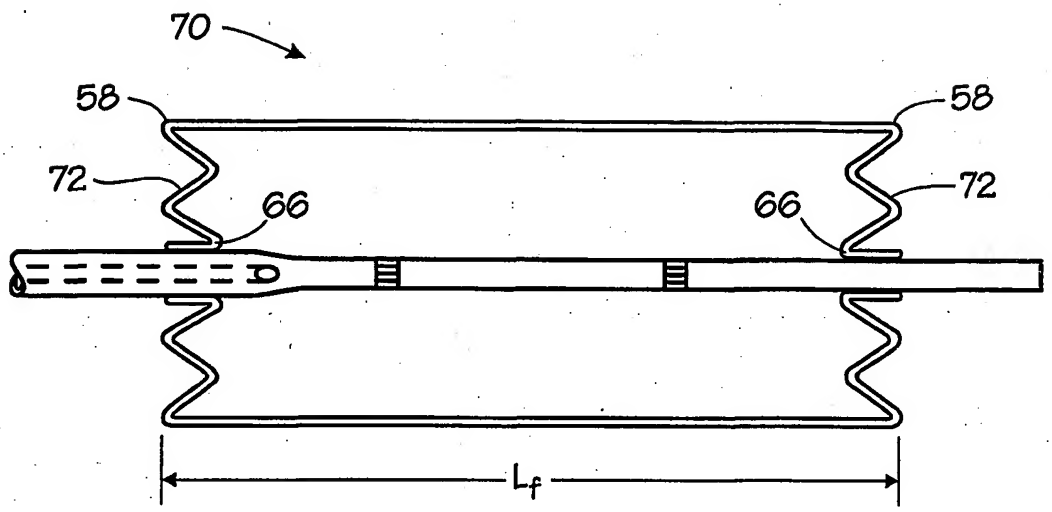

Fig. 6

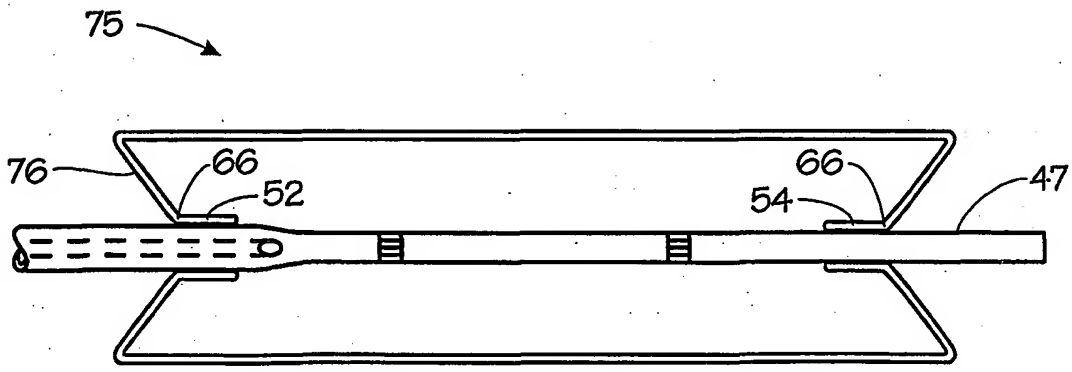

Fig. 7

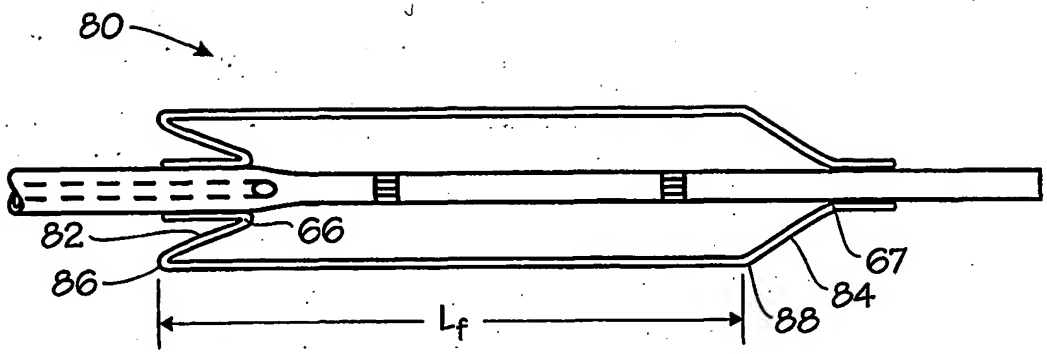

Fig. 8A

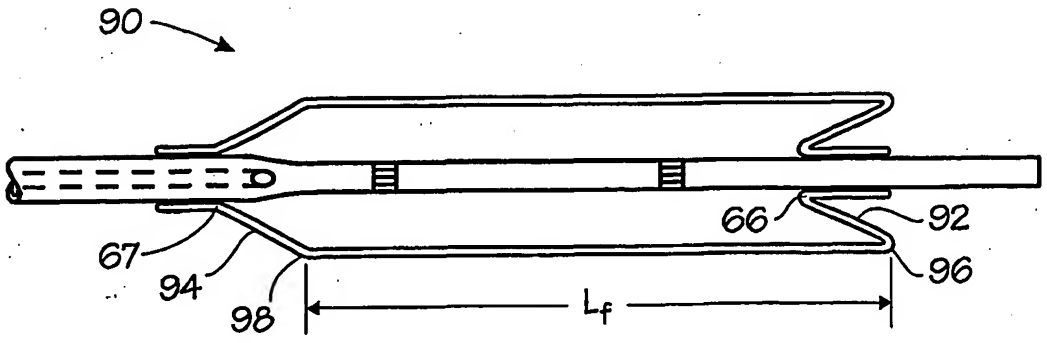

Fig. 8B

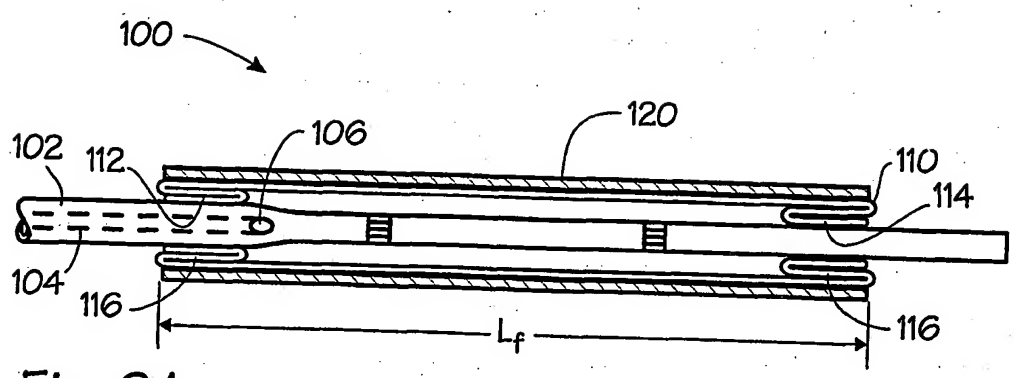

Fig. 9A

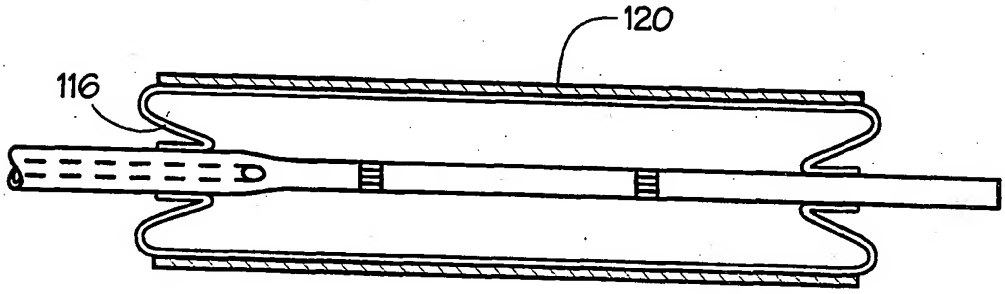

Fig. 9B

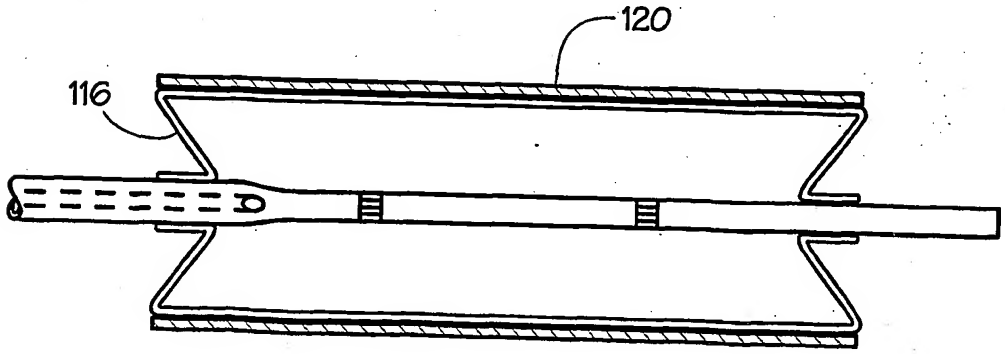

Fig. 9C

INTERNATIONAL SEARCH REPORT

national Application No
rcT/CA 00/01573

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 662 607 A (BOOTH ET AL.) 2 September 1997 (1997-09-02) abstract column 8, line 45 - line 46 column 8, line 53 - line 65; figures 2,6	1-5,9 11,12,31
X Y	EP 0 820 784 A (CORDIS CORP.) 28 January 1998 (1998-01-28) abstract column 3, line 28 - line 29; figure 2	15-23, 26-30, 35-39 11,12,31
X A	EP 0 489 507 A (SMITHS INDUSTRIES PLC.) 10 June 1992 (1992-06-10) abstract; figures 2,4	14-23, 26,39 1-13,24, 25,27-38

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 July 2001	19/07/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

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INTERNATIONAL SEARCH REPORT

national Application No
PCT/CA 00/01573

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 661 095 A (TALLER ET AL.) 28 April 1987 (1987-04-28) abstract; claim 1; figure 1	15,32
X	US 4 227 293 A (TAYLOR) 14 October 1980 (1980-10-14) abstract; figures 4-7	1-6
X	US 3 833 004 A (VAZQUEZ ET AL.) 3 September 1974 (1974-09-03) abstract column 3, line 21 - line 35; figure 1	14-23
E	WO 01 19443 A (SCIMED LIFE SYSTEMS, INC.) 22 March 2001 (2001-03-22) the whole document	1-39
A	EP 0 937 482 A (MEDTRONIC AVE., INC.) 25 August 1999 (1999-08-25) abstract; figures 2,3	1,14,15, 37,39
A	US 2 892 458 A (AUZIN ET AL.) 30 June 1959 (1959-06-30)	

INTERNATIONAL SEARCH REPORT

national Application No
PCT/CA 00/01573

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5662607 A	02-09-1997	US 5505698 A	09-04-1996
		US 5820586 A	13-10-1998
EP 0820784 A	28-01-1998	CA 2211249 A	24-01-1998
		US 6039721 A	21-03-2000
EP 0489507 A	10-06-1992	AU 647206 B	17-03-1994
		AU 8792591 A	11-06-1992
		CA 2056013 A	06-06-1992
		DE 69102982 D	25-08-1994
		DE 69102982 T	27-10-1994
		DK 489507 T	12-09-1994
		ES 2057782 T	16-10-1994
		GB 2250440 A,B	10-06-1992
		IE 913956 A	17-06-1992
		IL 100025 A	31-12-1995
		JP 4272766 A	29-09-1992
		US 5201310 A	13-04-1993
US 4661095 A	28-04-1987	CA 1239322 A	19-07-1988
		US 4737219 A	12-04-1988
US 4227293 A	14-10-1980	NONE	
US 3833004 A	03-09-1974	NONE	
WO 0119443 A	22-03-2001	US 6221042 B	24-04-2001
EP 0937482 A	25-08-1999	US 6176698 B	23-01-2001
US 2892458 A	30-06-1959	NONE	